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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,502	02/15/2002	Said M. Sebti	15101.01902	7653

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EXAMINER	
MARVICH, MARIA	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.A.M.

Office Action Summary	Application No.	Applicant(s)	
	10/049,502	SEBTI, SAID M.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending in this application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2, 5 drawn to a method of inhibiting growth of a cancerous cell comprising introducing a nucleic acid construct encoding the RhoB protein or a variant thereof into the cell.

Group II, claims 1 and 3-5 drawn to a method of inhibiting growth of a cancerous cell comprising introducing a RhoB protein or a variant thereof into the cell.

Group III, claim 6 drawn to a therapeutic composition comprising RhoB or a variant thereof.

Group IV, claim 7 drawn to a method of suppressing malignant transformation comprising administering a composition comprising RhoB protein or a variant thereof into the cell.

Group V, claim 8 drawn to a method of inhibiting tumor growth comprising administering a composition comprising RhoB protein or a variant thereof into the cell.

Group VI, claim 9 drawn to a method of inducing apoptosis comprising administering a composition comprising RhoB protein or a variant thereof into the cell.

Group VII, claim 10 drawn to a method of inhibiting oncogenic signaling comprising administering a composition comprising RhoB protein or a variant thereof into the cell.

Group VIII, claim 11 drawn to a prophylactic method of preventing malignant transformation comprising administering a composition comprising RhoB protein or a variant thereof into the cell.

Group IX, claim 12 drawn to a method of decreasing phosphorylated Akt, Erk1 or Erk2 comprising administering a composition comprising RhoB protein or a variant thereof into the cell.

Group X, claims 13-15 drawn to a nucleic acid construct comprising a region encoding an amino acid substantially similar to RhoB and a sequence directing the prenylation of RhoB and sequences directing expression of the RhoB.

Group XI, claim 16 drawn to a method of inhibiting growth of a cancer cell comprising administering a composition comprising RhoB protein or a variant thereof into the cell and an additional therapy.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Group I-XI do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The "special technical feature" of Group I is contacting the interior of a cell with an effective amount of a RhoB protein, which is shown by Chen et al

(Journal of Biological Chemistry Vol 275(24) pp 17974-17978 see e.g. page 17976 col 1, first paragraph), to lack novelty of inventive step and does not make a contribution over the prior art.

MPEP 1875.01(d) states "If multiple products, processes of manufacture or uses are claimed, the first invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)." As the special technical feature of Group I lacks novelty, the inventions of Group I-XI do not form a single general inventive concept and instead are composed of the following inventions. The technical feature of Group I differs from Group II in that Group I involves introduction of a nucleic acid encoding RhoB into a cell from which RhoB is made to contact the interior of the cell to inhibit growth of a cancerous cell whereas the technical feature of Group II involves introduction of RhoB protein which contacts the interior of the cell to inhibit growth of a cancerous cell whereas the technical feature. The technical feature of group III is drawn to a therapeutic composition comprising RhoB and can be used in any of Groups I-II, IV-IX and XI. Groups IV through IX and XI involve administration of RhoB but are each drawn to different technical feature as Group IV is drawn to a method of suppressing malignant transformation, Group V to inhibiting tumor growth, Group VI to inducing apoptosis, Group VII to inhibiting oncogenic signaling, Group VIII to preventing malignant transformation, Group IX to decreasing phosphorylated protein and Group XI to inhibiting growth of cancerous cells. Hence the method steps involve unique method steps and outcomes. Group XI and Group I are related in that both inhibit growth of a cancerous cell but Group XI includes additional therapy and thus Group I and XI involve different method steps and have different outcomes. The technical feature of Group X is drawn to a nucleic acid construct comprising RhoB.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai, In re Brouwer* and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Claim 1 links the inventions of Groups I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claim depending from or including all the limitations of the allowable linking claims is presented in the continuation or divisional application, the claims of the continuation of divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See MPEP 804.01.

Applicant is reminded that upon cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GERRY LEFFERS
PRIMARY EXAMINER

Maria B Marvich, PhD
Examiner
Art Unit 1636

February 10, 2004